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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,593	04/15/2004	Raymond Pratt	109536.159WO1	6645
26694	7590	01/10/2006	EXAMINER	
VENABLE LLP			CHANNAVAJALA, LAKSHMI SARADA	
P.O. BOX 34385			ART UNIT	PAPER NUMBER
WASHINGTON, DC 20045-9998			1615	

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/824,593

Applicant(s)

PRATT ET AL.

Examiner

Lakshmi S. Channavajjala

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9-28-05</u> . | 6) <input type="checkbox"/> Other: _____  |

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### **DETAILED ACTION**

Receipt of amendments, remarks and IDS all dated 9-28-05 is acknowledged.

Claims 1-24 are pending in the instant application.

#### ***Response to Arguments***

Applicant's arguments with respect to the rejection(s) of claim(s) 1-20 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as follows:

#### ***Claim Rejections - 35 USC § 103***

Claims 1-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,895,841 to Sugimoto et al in view of Ebel et al (Psychopharmacology) and Hurlbut.

Instant claims are directed to a method of treating substance abuse in a patient in need of comprising administering a therapeutically effective amount of choline esterase inhibitor compounds possessing the claimed structure. Sugimoto teaches the compounds of the instant claims (col. 2-3, in particular the compounds of col. 3), as also admitted in the instant specification (page 14, lines 11-12). Sugimoto teaches that the compounds described have a strong and highly selective anti-cholinesterase activity, increasing the amount of acetylcholine, exhibiting an excellent effect on a model with represent to disturbance of memory, and having a persistent activity (col. 1). Sugimoto teaches the compounds as useful for treating diseases such as Alzheimer's, Pick's Disease, ataxias etc., but not for treating the claimed substance abuse, as claimed.

Ebel et al teach cholinergic involvement in ethanol intoxication and withdrawal induced seizures susceptibility. A study of the enzymes of the cholinergic system has

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been investigated in discrete brain area in alcohol-dependent rats, which were still intoxicated or were undergoing withdrawal. Ebel states that the activity of cholinesterase is increased as a response to ethanol intoxication in certain regions of brain.

Hurlbut teaches that major drug-induced psychoses are due to drugs such as cocaine, amphetamines, phencyclidine, cannabinoids, anti-cholinergic compounds etc. Hurlbut teaches that in addition to supportive measures, reassurances, and benzodiazepine, specific antidotes such as physostigmine for anti-cholinergic poisoning or urinary acidification to enhance excretion of amphetamines or phencyclidine in some patients.

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to use the acetylcholine esterase inhibitors of Sugimoto for treating ethanol induced withdrawal (Ebel) or toxicity induced by drugs such as cocaine, amphetamines etc., (Hurlbut) because both Ebel and Hurlbut suggest increased cholinesterase activity due to the intoxication (ethanol) or drug usage (Hurlbut) and hence in a perturbation in the synthetic capacity of acetylcholine and Hurlbut suggests treating the drug induced psychoses and the related poisoning with cholinesterase inhibitors. Thus, a skilled artisan would have exhibited to reduce the drug withdrawal symptoms as well as the associated poisoning with the cholinesterase inhibiting compounds of Sugimoto. Further, optimizing the amounts of compounds and administering by appropriate routes depending on the type of substance abuse or addiction, patient population involved etc., are within the scope of a skilled artisan because Sugimoto suggests various dosages and routes of administration.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala  
Examiner  
Art Unit 1615  
January 9, 2006